WHY FEDERAL STEM CELL POLICY MUST BE EXPANDED

Embryonic stem cell research offers one of the most promising avenues to accomplish JDRF's ultimate goal of a cure for juvenile diabetes. JDRF had hoped that the August 2001 Federal stem cell policy would be the beginning of intense scientific effort to reach this goal. But the objective truth echoed by every leading researcher in the field is that the policy, while well intentioned, will not permit research to advance at the pace it can and must; in fact, the policy is actually *slowing* the scientific progress in this area that the President himself championed.

The call for an expansion of Federal stem cell policy reflects what scientists have learned since the August 2001 announcement. Our understanding of the science has progressed since then, and knowledge of the NIH-approved stem cell lines has grown much deeper. It is time to adjust the Federal policy so that it accurately represents the latest understanding of the science. The simple, inescapable fact – acknowledged by the Federal government itself – is that access to additional stem cell lines will accelerate the potential breakthroughs required to cure not only diabetes, but a range of diseases afflicting millions of Americans.

THE PROBLEMS WITH THE EXISTING POLICY ARE NUMEROUS AND PERVASIVE. THEY INCLUDE:

1) Of the original 78 stem cell derivations that were declared eligible for US Federal funding under the August 2001 policy, only 22 are actually available for distribution and study[1].

2) Because the NIH-approved stem cell lines were developed using science that has since seen significant improvements and progress, they may prove to be far more limited in their utility than lines created more recently.

3) The NIH-approved lines lack the genetic diversity scientists need to do research that could create therapeutic treatments for millions of Americans.

4) Because human embryonic stem cells are heterogeneous, with some showing a greater propensity to become certain types of cells, a limited number of stem cell lines can decrease the breadth of research opportunities for scientists.

5) The absence of disease-specific stem cell lines eligible for Federal funding means that the current policy is limiting stem cell research from beginning on dozens of genetic diseases such as Duchenne muscular dystrophy and Huntington's Disease, potentially adding years to the discovery of treatments for millions of Americans.

6) All the NIH-approved lines were isolated in contact with mouse 'feeder' cells. As a result, the FDA must consider any therapies developed using these stem cells as xenotransplants, creating a huge hurdle that discourages the biotech and pharmaceutical industries from developing treatments utilizing those lines.

7) Policy limits on stem cell research discourage scientists from entering the field.

[1] NIH Human Embryonic Stem Cell Registry http://stemcells.nih.gov/research/registry/ January 10, 2005.

JDRF Juvenile Diabetes Research Foundation International

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